

Message Text

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ACTION EB-08

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NSAE-00 AGRE-00 TRSE-00 H-01 ITC-01 /053 W
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TO SECSTATE WASHDC 9003
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E.O. 11652: NA
TAGS: BEXP, JA
SUBJECT: TRADE FACILITATION COMMITTEE: CASE NO. 4 -
ABBOTT LABORATORIES

REF: (A) STATE 128606, (B) TOKYO 4018, (C) STATE 155598

SUMMARY: ABBOTT TFC CASE IS TURNING OUT TO BE A
COMPLEX EXAMPLE OF ADAPTING TFC PRINCIPLE TO A
JAPANESE MINISTRY THAT ONLY DIMLY PERCEIVES ITS
RELATIONSHIP TO FOREIGN TRADE POLICY ISSUES. MHW
OFFICIALS HAVE GIVEN US SOME ADDITIONAL INFORMATION
ON THE ABBOTT CASE WHICH, TOGETHER WITH INFORMATION
FROM PRIVATE SOURCES, SUGGESTS THAT ABBOTT'S POSITION
IS NOT AS CLEAR-CUT AS WE MIGHT HAVE ASSUMED. IN-
DEPENDENT CONFIRMATION OF AUSRIA'S DIAGNOSTIC VALUE
WOULD BE DESIRABLE. WE WOULD ALSO ADVISE ASKING
ABBOTT FOR ELABORATION ON MHW COMMENTS CONTAINED PARAS
3 AND 4 BELOW; WE NEED DOCUMENTATION--EVEN INTERNAL
MEMCONS--CONCERNING DETAILS OF 1974 APPLICATION
WITHDRAWAL AND ALLEGED JAPAN RED CROSS REQUEST TO
MHW. IN THE MEANTIME, WE ARE BROADENING OUR HIGH-LEVEL
CONTACTS WITHIN MHW TO HANDLE CASES LIKE ABBOTT MORE
EFFECTIVELY AND WE ARE PREPARED TO PRESS THE JAPANESE
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FURTHER ON THIS ISSUE--BUT NOT IN A WAY THAT WILL RISK
MAKING THE PAROCHIAL MHW BUREAUCRATS MORE TRUCULENT
THAN THEY ALREADY ARE. END SUMMARY.

1. AFTER TRANSMITTING INFORMATION CONTAINED IN REFTEL A
THROUGH FORMAL TFC CHANNEL (HANAOKA), WE ARRANGED MEETING
WITH MHW SECRETARIAT'S INTERNATIONAL AFFAIRS DIVISION

DIRECTOR KANEDA ON MAY 30 TO SEE IF MHW MIGHT PROVE MORE AMENABLE TO A DIRECT APPROACH BY US ON ABBOTT AND RELATED CASES. MEETING WAS SET BY EMBASSY SCICOUNS, WHO IS USUAL CHANNEL FOR COMMUNICATIONS WITH KANEDA. KANEDA TOLD US THAT HE HAD NOT HEARD OF EITHER THE ABBOTT LABS CASE OR THE TRADE FACILITATION COMMITTEE AND WONDERED IF MHW OUGHT TO BE INVOLVED IN "TRADE DISPUTES" SINCE ITS CONCERNS ARE "STRICTLY TECHNICAL." WE REPLIED THAT MHW'S INVOLVEMENT WITH IMPORTED PHARMACEUTICALS AND MEDICAL EQUIPMENT HAS UNAVOIDABLE TRADE IMPLICATIONS AND REQUESTED KANEDA'S ASSISTANCE IN RESOLVING THE ABBOTT LABS CASE. KANEDA PROMISED TO STUDY THE MATERIAL WE GAVE HIM AND TO MAKE INQUIRIES.

2. AT KANEDA'S REQUEST, WE MET WITH HIM AND PHARMACEUTICAL AFFAIRS BUREAU'S DR. SAITO ON JUNE 7. AFTER MAKING IT CLEAR THAT THEIR REPLY WAS THROUGH USUAL SCIENCE CHANNEL AND NOT RELATED TO THE TFC, KANEDA REVIEWED MUCH OF WHAT WAS IN HANAOKA'S INITIAL REPLY OF MARCH 7, BUT HAD ADDITIONAL INFORMATION. HE NOTED THAT A HEPATITIS STANDARDS PANEL TO CONSIDER THE ABBOTT AUSRIA APPLICATION IS TO BE ESTABLISHED NEXT YEAR, AND THAT A FINAL DECISION ON AUSRIA WOULD HAVE TO AWAIT THEIR DELIBERATIONS. FUNDS FOR THE PANEL ARE TO BE INCLUDED IN THE JFY 1979 BUDGET. EVEN IF PANEL CONCLUDES WORK ON SCHEDULE (ESTIMATED TO TAKE ONE YEAR), FINAL APPROVAL WOULD THEN BE REQUIRED LIMITED OFFICIAL USE

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FROM THE CENTRAL PHARMACEUTICAL COUNCIL.

3. IN EFFORT TO DETERMINE WHY IT HAD TAKEN SO LONG TO ESTABLISH STANDARDS PANEL WHEN APPLICATION HAD BEEN FILED IN 1974, EMBOFFS LEARNED THAT PHARMACEUTICAL BUREAU HAD RECEIVED APPLICATION IN 1973 BUT THAT IT WAS WITHDRAWN "VOLUNTARILY" BY ABBOTT IN OCTOBER 1974 AND THEN RESUBMITTED IN MAY 1976. THEREFORE, APPLICATION IS CONSIDERED TO HAVE BEEN FILED ONLY IN 1976. (DAIN-ABOT'S DR. SMITH NOTED THAT THIS WITHDRAWAL WAS MADE AT THE REQUEST OF MHW.)

4. WHEN ASKED WHY NEW DRUG APPROVAL WAS REQUIRED FOR A LABORATORY TEST, SAITO ANSWERED THAT HEPATITIS B CASES CAUSED OR ALLEGED TO BE CAUSED BY BLOOD TRANSFUSIONS WERE RESULTING IN A NUMBER OF LAW SUITS AGAINST DOCTORS AND HOSPITALS, AND MHW WANTS TO INSURE THAT EVERY POSSIBLE REVIEW IS MADE TO GUARANTEE VALIDITY OF ANY NEW DIAGNOSTIC TEST. EMBOFF NOTED THAT AUSRIA TESTS SEEMED TO BE IN WIDE USE AMONG PRIVATE CLINICS AND THAT ABBOTT DATA ON THIS WERE AVAILABLE TO MHW. EMBOFF ALSO ASKED THAT MHW AUTHORIZE AUSRIA USE BY JAPAN RED CROSS (JRC)

THROUGH ADMINISTRATIVE GUIDANCE, AS HAD BEEN DONE BY MHW FOR AGGLUTINATION TEST NOW IN USE BY JRC. KANEDA THEN NOTED THAT--CONTRARY TO ABBOTT'S CLAIM--THE JRC HAD NOT ACTUALLY SOUGHT MHW PERMISSION TO USE AUSRIA. (THE FOLLOWING DAY, SMITH OF DAINABOT TOLD US THAT THERE IS, IN FACT, NO WRITTEN EVIDENCE OF A JRC REQUEST TO MHW FOR AUSRIA. JRC ONLY "TOLD" ABBOTT THAT THEY HAD MADE SUCH A REQUEST.) FINALLY, SAITO TOLD US THAT PHARMACEUTICAL AFFAIRS BUREAU PERSONNEL HAD CONVEYED THESE POINTS TO DIRECTOR OF R&D FOR DAINABOT IN APRIL 1978.

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5. IN ATTEMPT TO OBTAIN INDEPENDENT VIEW OF NEED FOR TEST, SCICOUNS LATER TALKED TO AMERICAN HEMATOLOGIST WORKING ON HEPATITIS RESEARCH AT JRC BLOOD TRANSFUSION CENTER. U.S. SCIENTIST HIMSELF WAS UNAWARE OF AUSRIA TEST, BUT CHECKED WITH SEVERAL PRIVATE AND PUBLIC SERVICE PHYSICIANS INVOLVED WITH HEPATITIS B. CONSENSUS WAS THAT AUSRIA TEST IS A LITTLE MORE EXPENSIVE THAN AGGLUTINATION WHILE BEING SLIGHTLY MORE SENSITIVE AND ACCURATE, AND THAT IT REQUIRES MORE COMPLICATED LABORATORY PROCEDURES. SCICOUNS ALSO TALKED TO PHYSICIAN REPUTED TO BE JAPAN'S FOREMOST EXPERT ON HEPATITIS AND WAS TOLD THAT AUSRIA TEST HAD NOT YET BEEN PROVEN EFFECTIVE IN DETECTING HBS ANTIGEN STRAIN PECULIAR TO JAPANESE.

6. COMMENT: ABOVE STATEMENTS BY MHW OFFICIALS AND PRIVATE PHYSICIANS CAUSE US TO WONDER WHETHER ABBOTT POSITION IS AS CLEAR-CUT AS WE HAD BEEN LED TO BELIEVE. AT THIS POINT IT WOULD BE HELPFUL TO GO BACK TO ABBOTT AND OBTAIN CLARIFICATION ON THE EVIDENT DIFFERENCES IN

POINT OF VIEW BETWEEN IT AND MHW. MHW HAS NOT BEEN AS FORTHCOMING AS IT MIGHT HAVE, AND WE ARE PREPARED TO PUT MORE PRESSURE ON IT IF THERE IS A CASE HERE FOR DOING SO. WE ALSO PLAN TO WIDEN OUR CONTACTS WITHIN THE MHW BUREAUCRACY TO GIVE US MORE FLEXIBILITY IN DEALING WITH LIMITED OFFICIAL USE

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ABBOTT AND SIMILAR PROBLEMS. (E/C MIN'S PLANNED CALL ON PHARMACEUTICAL AFFAIRS BUREAU DIR GEN NAKANO SHOULD BE OF CONSIDERABLE HELP.) HOWEVER, THESE EFFORTS WILL BE MEANINGFUL ONLY IF WE HAVE DEVELOPED A TRULY STRONG CASE BEFORE WE PUSH THIS ALREADY DEFENSIVE, PAROCHIAL BUREAUCRACY TO A DEGREE THAT WOULD CAUSE IT TO CIRCLE ITS WAGONS EVEN MORE TIGHTLY AGAINST "FOREIGN PRESSURE." CASE WOULD BE STRENGTHENED IF USG (FROM, SAY, USPHS COMMUNICABLE DISEASE CENTER, STATE'S O/MED, OR SIMILAR ENTITY) COULD PROVIDE AN INDEPENDENT CONFIRMATION OF THE VALUE OF AUSRIA AS A DIAGNOSTIC TOOL FOR HEPATITIS B. MANSFIELD

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